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Anita Johnson

Appl No.

: 10/820,480

Confirmation No. 7287

Applicant

: Claudio P. Plaza, et al.

Filed

: April 2, 2004

Title

: IRRIGATED CATHETER HAVING A POROUS TIP ELECTRODE

TC/A.U.

: 3739

Examiner

: Michael F. Peffley

Docket No.

: 51991/W112

Customer No.

: 23363

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Post Office Box 7068 Pasadena, CA 91109-7068 October 8, 2009

Commissioner:

Applicant requests review of the final rejection of claims 1-30 in the above-identified application. No amendments are being filed with this Request. This Request is being filed with a Notice of Appeal. The review is requested for the reasons stated below.

In the Final rejection dated June 10, 2009 and the Advisory action dated September 21, 2009, the Examiner maintained the rejection of claims 1-30 under 35 U.S.C. §103(a) as allegedly obvious over Moaddeb, et al. (U.S. Patent No. 6,405,078) in view of Skalsky, et al. (U.S. Patent No. 4,844,099). In maintaining this rejection, the Examiner argues that "[i]t is improper for [A]pplicant to assume that the [Skalsky] electrode must be used in the same manner (i.e. to attach to tissue) when combined with the [Moaddeb] reference," and that "[t]he skilled artisan would not be required to use [the Skalsky] construction in the exact same manner and would realize that any porous electrode may be fabricated in [the Skalsky] manner and continue to be

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used for its intended purpose." Office action, page 4. Applicant respectfully traverses this rejection.

As noted in MPEP §2143.02, obviousness requires a reasonable expectation of success, which can be shown if "all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art." Here, the combination of Moaddeb and Skalsky would result in a significant change in the respective functions of the claimed elements. In particular, as noted in Applicant's previous responses, Skalsky discloses a pacing lead that is designed to remain in the heart. In order to accomplish this, the Skalsky lead is designed to facilitate attachment of the lead to tissue by promoting tissue ingrowth. See column 2, line 54 to column 3, line 8. Given this disclosure in Skalsky, those of ordinary skill in the art would have predicted that the Skalsky structure would promote tissue ingrowth and affix to tissue. As the catheter disclosed in Moaddeb is designed for temporary use during a relatively short procedure, a structure such as that described in Skalsky that promotes tissue ingrowth and affixes to tissue would significantly alter the function of the Moaddeb device.

Moreover, as Skalsky is directed to a pacing lead that attaches to tissue through tissue ingrowth, those of ordinary skill in the art would have predicted that replacing the electrode of Moaddeb with a structure similar to that described in Skalsky would result in a structure that attaches to tissue through tissue ingrowth. As such, those of ordinary skill in the art looking for ideas to improve the Moaddeb catheter would not have predicted any beneficial result from the modification suggested by the Examiner. Indeed, those of ordinary skill would predict that the resulting device would attach to tissue through tissue ingrowth, significantly altering the function of the Moaddeb device, and rendering the Moaddeb catheter non-operational.

Furthermore, although the examiner asserts that "[t]he skilled artisan...would realize that any porous electrode may be fabricated in [the Skalsky] manner and continue to be used for its intended purpose," the Examiner appears to also argue that those of ordinary skill in the art would have used the Skalsky configuration for a purpose *other than* its intended purpose. In

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particular, the intended purpose of the Skalsky device is to promote tissue ingrowth in order to affix a pacing lead to tissue. However, the Examiner argues that those of ordinary skill in the art would have used the Skalsky device in the Moaddeb device for a different purpose, i.e., as an electrode on a catheter used for temporary and relatively short procedures. As the Moaddeb catheter is intended for temporary and relatively short procedures, an electrode that affixes to tissue would render the Moaddeb catheter non-operational.

Notably, the Examiner does not argue that a device that affixes to tissue would not significantly alter the function of the Moaddeb device. Instead, the Examiner argues that those of ordinary skill in the art would not have been required to use the Skalsky device within the Moaddeb device "in the exact same manner." Office action, page 4. However, as noted in MPEP §2143.02, to establish obviousness through a reasonable expectation of success, the Examiner must show that "one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions." Here, using the Skalsky device in the Moaddeb catheter would necessarily result in a material change in the function of the Skalsky device. Specifically, as the Skalsky device functions to affix a lead to tissue, its incorporation into the Moaddeb device, which functions to perform temporary and short procedures would require changing the Skalsky device such that it does not attach to tissue. As such, the Skalsky device would no longer perform its intended function. Conversely, if the function of the Skalsky device remains unchanged, the function of the Moaddeb catheter would be materially altered since the Skalsky device functions to attach to tissue which would prevent the Moaddeb device from being used for temporary procedures. Accordingly, those of ordinary skill in the art could not have combined the Skalsky lead with the Moaddeb catheter with no change in their respective functions. Therefore, those of ordinary skill in the art would not have combined

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Moaddeb and Skalsky in the manner suggested by the Examiner, and claims 1-30 are allowable over those references. Applicant therefore respectfully requests reversal of the rejection of the pending claims.

Respectfully submitted,

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